From: Mark Miller
To: Susanne Hiland; James Perkins
CC: Tony Nation; John Marakas - JGMARAK
Sent: 9/2/2011 4:34:19 PM
Subject: Proposed Rule Change by Ohio Board of Pharmacy
Attachments: 2011-Rule-Review-Text-Proposed-Final (2).pdf

Dear Friends,

Please review the proposed rule changes by the State of Ohio Board of Pharmacy in the attachment. I would specifically refer you to 4729-5-20 (D). In the change, pharmacists will be required to review an OARRS report on patients that fall within several categories. I believe this will present a significant burden and liability to our pharmacists and an unjustified delay to our patients.

Thanks,

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Save Money. Live Better.

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FULL TEXT SHOWING CHANGES

UNDERLINED = Added New Language **LINED THROUGH** = Removed Old Language

4729-1-02 NOTICE OF MEETINGS

Any person may obtain the time and place of all regularly scheduled meetings and the time, place, and purpose of all special meetings of the state board of pharmacy, as required by division (F) of section 121.22 of the Revised Code, by:

~~(A) Regular mail, upon written request to the state board of pharmacy.~~

~~(1) Written requests shall include the name, mailing address, and telephone number of the person making the request.~~

~~(2) Written requests shall be accompanied by a service fee of twenty-five dollars which shall be valid for the fiscal year of July first through June thirtieth.~~

~~(3) Notice for the annual renewal of this request will be sent by the board of pharmacy by June first of each year and shall be due no later than July thirty-first of each year.~~

(~~B~~A) Calling the telephone number of the state board of pharmacy between the normal business hours of eight a.m. to four-thirty p.m., Monday through Friday, ~~legal~~ state holidays excepted.

(~~C~~B) Consulting the official record of all board of pharmacy regularly scheduled and special meetings located at office of the state board of pharmacy.

(~~D~~C) Viewing the state board of pharmacy's world wide web home page.

(~~E~~D) Requesting the information to be sent by the state board of pharmacy by e-mail.

4729-1-03 PUBLIC RECORDS

(A) Public records, as defined in section 149.43 of the Revised Code, maintained by the state board of pharmacy, are available for inspection at the board office between the hours of eight a.m. and four-thirty p.m., Monday through Friday of each week, state holidays excluded.

(B) Copies of public records will be made available at cost pursuant to the following conditions:

(1) A ~~written~~ request shall be submitted to the board of pharmacy specifying which records are to be copied, the number of copies, and the date that such copies are needed.

(2) Upon receipt of ~~the written~~ a request, the board shall determine the cost ~~and the amount of time necessary~~ to provide such copies. The copies will be prepared and provided only when the board has been reimbursed for the cost.

(C) The names and addresses of persons licensed or registered with the board will be provided at cost pursuant to the following conditions.

(1) A ~~written~~ request is submitted to the board of pharmacy specifying:

(a) The names and addresses that are to be provided;

(b) The form and format in which the records are to be provided;

(c) The date that the names and addresses are needed.

(2) Upon receipt of ~~the written~~ a request, the board shall determine the cost ~~and the amount of time necessary~~ to provide the names and addresses. The names and addresses will be prepared and provided only when the board has been reimbursed for the cost.

4729-3-01 DEFINITIONS

As used in Chapter 4729-3 of the Administrative Code:

(A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

(B) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of an internship program.

(1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to paragraph (~~B~~C) of rule 4729-3-05 of the Administrative Code.

(2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty.

(3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.

(C) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.

(D) "In good standing" means that the preceptor has not been denied the privilege of supervising interns by the board.

(E) "Statement of Preceptor" is a form provided by the state board of pharmacy that identifies the preceptor and internship site for a pharmacy intern.

(F) "Practical Experience Affidavit" is a form provided by the state board of pharmacy used to submit evidence of practical experience for internship credit pursuant to rule 4729-3-06 of the Administrative Code.

(G) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy.

4729-3-05 INTERNSHIP CREDIT

(A) The pharmacy internship credit requirement for the licensure examinations shall be deemed satisfactorily completed when the intern has:

(1) Successfully graduated after December 31, 2006 with a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the "Accreditation Council for Pharmacy Education (A.C.P.E.)" and the state board of pharmacy; or

(2) Obtained a total of at least one thousand five hundred hours of documented supervised practical experience accepted by the state board of pharmacy which may include any hours:

(a) Documented on a practical experience affidavit pursuant to rule 4729-3-06 of the Administrative Code; or

(b) Worked in another state where that state board of pharmacy submits official verification of the actual practical experience contact hours worked to the Ohio board of pharmacy.

(B) No internship credit shall be granted by the board for practical experience until a foreign pharmacy graduate has established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and has established proficiency in spoken English by successfully completing the ~~"Test of Spoken English (TSE)" or its board approved equivalent~~ "Test of Spoken English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule 4729-5-34 of the Administrative Code.

(C) Practical experience obtained pursuant to paragraph (A)(2)(a) of this rule may include up to five hundred hours of internship credit at a site other than a pharmacy licensed as a terminal distributor of dangerous drugs (e.g., manufacturing, research, consulting, drug information, and drug utilization review). To receive credit for such experience, a formal request must be submitted to the director of internship for approval prior to beginning the experience in these areas. The request shall include a detailed description of the contemplated internship with respect to time, place, duties, responsibilities, professional supervision, and the person supervising the experience. The request must be signed by both the intern and the person supervising the experience and returned with a completed statement of preceptor form. If approved by the board, the hours must be documented using a practical experience affidavit pursuant to rule 4729-3-06.

(D) Internship credit may be denied for the practical experience accumulated when an intern is found to be guilty of violation(s) pursuant to section 4729.16 of the Revised Code.

4729-3-09 EXPIRATION OF PHARMACY INTERN CERTIFICATE

(A) When a candidate receives his/her first identification card to practice as a pharmacist, his/her registration as a pharmacy intern terminates.

(B) A pharmacy intern, other than a graduate pharmacist intern, must immediately notify his/her current employer and any subsequent employer where practicing as a pharmacy intern if he/she is no longer enrolled in a school of pharmacy. The person should immediately return his/her pharmacy intern certificate and pocket identification card to the state board of pharmacy.

4729-4-03 QUALIFIED PHARMACY TECHNICIAN TRAINING PROGRAM

A pharmacy technician training program pursuant to division (~~E~~F) of section 4729.42 of the Revised Code shall be of appropriate breadth and depth, clearly addressing the competencies for a technician to safely and effectively work in that particular setting and shall include at a minimum the following:

(A) The applicable practice areas specified in division (B) of section 4729.42 of the Revised Code;

(B) Pharmacy terminology;

(C) Basic drug information;

(D) Basic calculations;

(E) Quality control procedures;

(F) State and federal laws, rules, and regulations regarding:

(1) Qualified pharmacy technician duties;

(2) Pharmacist duties;

(3) Pharmacy intern duties;

(4) Prescription or drug order processing procedures;

(5) Drug record keeping requirements;

(6) Patient confidentiality;

(7) Security requirements;

(8) Storage requirements.

4729-5-01 DEFINITIONS

As used in Chapter 4729. of the Revised Code:

(A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.

(B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.

(C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

(D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.

(E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.

(F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.

(G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.

(H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a board approved electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.

(I) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(J) "Preprinted order" is defined as a patient specific, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the Administrative Code.

(K) "Standing order" will mean the same as the term "protocol".

(L) "Protocol" is defined as:

(1) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or

(2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases; or

(3) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the treatment guidelines prior to implementation. A list of the board approved drugs used in the treatment guidelines shall be displayed on the pharmacy board web site (www.pharmacy.ohio.gov). To be considered for approval by the board, the treatment guidelines must meet the following requirements:

(a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.

(b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.

(c) The treatment guidelines:

(i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;

(ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;

(iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;

(iv) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;

(v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;

(vi) Can be performed without requiring the exercise of medical judgment;

(vii) Will lead to results that are reasonably predictable and safe;

(viii) Can be performed safely without repeated medical assessments;

(ix) If performed improperly, would not present a danger of immediate and serious harm to the patient.

A protocol may be used only by individuals authorized by law to administer the drugs and to perform the procedures included in the protocol.

Protocols submitted for approval by the state board of pharmacy may be reviewed with the appropriate health care related board prior to any approval by the state board of pharmacy.

(M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.

(N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug.

(1) A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A thumbprint reader or other biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(O) "Originating pharmacy", as it relates to central fill pharmacies, means the pharmacy that received the original prescription.

(P) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(Q) "OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(R) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

4729-5-07 RECOGNIZED AND APPROVED COLLEGES OF PHARMACY

(A) To be recognized and approved by the state board of pharmacy, a school of pharmacy shall meet the requirements as set forth by the board. The board may utilize the reports, requirements, and recommendations of any recognized accrediting organization or higher education governing board in determining the requirements. The board of pharmacy shall take into consideration, but not be bound by, accreditation standards established by the "Accreditation Council for Pharmacy Education."

(B) For the purpose of satisfying the requirements of division (C) of section 4729.08 of the Revised Code, graduates of a school of pharmacy located outside the United States shall establish educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and by establishing proficiency in spoken English by obtaining the minimum scores required by rule 4729-5-34 of the Administrative Code on the ~~"Test of Spoken English (TSE)" or the~~ "Test of English as a Foreign Language, Internet-based test (TOEFL iBT). "

(C) The term "United States," as used in paragraph (B) of this rule, shall be deemed to include all states of the United States, the District of Columbia, and all territories and any commonwealths.

4729-5-20 PROSPECTIVE DRUG UTILIZATION REVIEW

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment;

(9) Food-nutritional supplements-drug interactions.

(B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's report if applicable and available, and/or consulting with the prescriber and/or counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information;

(3) United States pharmacopoeia drug information;

(4) American medical association evaluations.

(D) Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person:

(1) Receiving reported drugs from multiple prescribers;

(2) Receiving reported drugs for more than twelve weeks;

(3) Abusing or misusing reported drugs (i.e. over-utilization, early refills, or appears overly sedated or intoxicated upon presenting a prescription for a reported drug);

(4) Requesting a reported drug by specific name, street name, color, or identifying marks;

(5) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or

(6) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.

In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

4729-5-25 DISPENSING AND COMPOUNDING OF DRUGS

(A) Only a pharmacist or pharmacy intern under the personal supervision of a pharmacist is permitted to engage in dispensing and compounding.

(B) A ~~person~~ qualified pharmacy technician pursuant to section 4729.42 of the Revised Code, not a pharmacist or intern under the personal supervision of a pharmacist, may assist a pharmacist in the compounding and dispensing of drugs in accordance with section 4729.01 of the Revised Code and according to the following requirements:

(1) May not engage in any procedure requiring professional judgment. The pharmacist is responsible for the drug compounded or dispensed.

(2) The system of drug distribution must provide exact control and assign immediate responsibility only to a pharmacist accountable at every point in the system between receipt of the order for a drug and final delivery for administration or use by the patient.

(3) May not engage in any procedure contrary to the intent of the statutes and rules regulating the dispensing and compounding of drugs.

~~(4) All such persons must not have any pending charges or prior convictions of any state or federal pharmacy or drug laws, or be addicted to or abusing alcohol or drugs, or impaired physically or mentally to such a degree as to render him/her unfit.~~

(C) No dangerous drug, as defined in section 4729.01 of the Revised Code, shall be sold, offered for sale, or dispensed by means of any mechanical device unless such device is approved by the state board of pharmacy.

4729-5-26 PARTIAL DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES

At the time of partial dispensing of a schedule II controlled substance prescription for a "terminally ill" patient or a patient residing in a "long term care facility", in accordance with ~~section~~ 21 C.F.R. 1306.13 ~~of the Code of Federal Regulations~~, the following must be observed:

(A) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription.

(B) The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.

(C) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of this partial dispensing if different, and the manual initials of the dispensing pharmacist.

(D) If an alternate record keeping system is being used and the system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.

(1) A notation must also be made in the database that identifies this new prescription number as a partial dispensing and provides the serial number of the original prescription.

(2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription.

(E) The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.

(F) All partial dispensings of schedule II controlled substances must occur within sixty days from the date of issuance of the prescription by the prescriber.

4729-5-30 MANNER OF ISSUANCE OF A PRESCRIPTION

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) All prescriptions issued by a prescriber shall:

(1) Be dated as of and on the day when issued.

(2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber.

(3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.

(4) Indicate the full name and residential address of the patient.

(5) Indicate the drug name and strength.

(6) Indicate the quantity to dispense.

(7) Indicate the appropriate and explicit directions for use.

(8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.

(9) Not authorize any refills for schedule II controlled substances.

(10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

(11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.

(12) Identify the trade name or generic name of the drug(s) in a compounded prescription.

(13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

(14) For prescriptions issued to a patient by a prescriber, be:

(a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.

(b) Issued in compliance with rule 4729-5-13 of the Administrative Code.

(15) For a controlled substance, indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05 (enacted on June 23, 2005).

(16) If issued by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with prescriptive authority, contain the nurse's prescriber number found on the certificate to prescribe issued by the state board of nursing pursuant to rule 4723-9-09 of the Administrative Code.

(17) If issued by a physician assistant with prescriptive authority, contain the certificate number of the physician assistant's certificate to prescribe pursuant to rule 4730-2-07 of the Administrative Code.

(18) Be issued in compliance with all applicable federal and state laws, rules, and regulations.

(C) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(D) Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:

(1) A pharmacist.

(2) A recording device within the pharmacy if the pharmacist is unavailable. The pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.

The prescriber's agent must provide his/her full name when transmitting an oral prescription.

(E) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:

(1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

(3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

(a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.

(b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.

(c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code.

(4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.

(5) The facsimile of the prescription must include header information identifying the origin of the facsimile.

(F) A prescription may be transmitted by means of a board approved electronic prescription transmission system provided that:

(1) The system requires positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.

(2) The computer data is retained for a period of three years at the prescriber's office.

(3) An electronic prescription transmission system meeting the requirements of 21 C.F.R. 1311 <u>for both controlled substance and non-controlled substance prescriptions</u> shall be considered approved by the state board of pharmacy.

(G) Pursuant to section 4729.38 of the Revised Code if a prescriber does not want a pharmacist to select a generically equivalent drug the prescriber must handwrite "dispense as written" or "DAW" on the prescription, or if ordering electronically or orally the prescriber specifies that the prescribed drug is medically necessary.

4729-5-33 EXAMINATION APPLICATION FOR REGISTRATION AS PHARMACIST

(A) Every person desiring to apply to take the examinations for registration as a pharmacist shall submit the required application materials and fees to the national association of boards of pharmacy and the following to the state board of pharmacy:

(1) A completed application form as provided by the board;

(2) A head and shoulders photograph taken within the previous six months;

(3) Required fee;

(4) A certificate of education completed and certified by an approved school of pharmacy pursuant to rule 4729-5-07 of the Administrative Code documenting the successful graduation of the applicant with a doctor of pharmacy degree obtained after December 31, 2006; or

(5) All items in paragraphs (A)(1) to (A)(3) of this rule, one thousand five hundred hours of supervised practical experience pursuant to paragraph (A)(2) of rule 4729-3-05 of the Administrative Code; and

(a) A certificate of education completed and certified by an approved school of pharmacy documenting the successful graduation of the applicant; or

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the ~~"Test of Spoken English (TSE)" or its board approved equivalent~~ "Test of Spoken English as a Foreign Language, Internet-based test (TOEFL iBT)" pursuant to rule 4729-5-34 of the Administrative Code.

(B) The state board of pharmacy may make an applicant eligible to take the examinations as soon as the board receives all the required items set forth in paragraphs (A)(1) to (A)(3) and paragraph (A)(4) or (A)(5) of this rule.

(C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny admission to the licensure examination.

4729-9-06 DISPOSAL OF DANGEROUS DRUGS WHICH ARE CONTROLLED SUBSTANCES

(A) Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances may dispose of such drugs by the following procedure:

(1) If the person is a registrant or prescriber required to keep records pursuant to Chapters 3719. and 4729. of the Revised Code, the responsible pharmacist or prescriber shall send the state board of pharmacy a list of the dangerous drugs which are controlled substances containing the name, strength, dosage form, and quantity to be disposed of.

(2) If the person is not a registrant or prescriber, he shall submit to the state board of pharmacy a letter stating:

(a) The full name and address of the person possessing the dangerous drugs which are controlled substances to be disposed of;

(b) The name, strength, dosage form, and quantity of each controlled substance;

(c) How the applicant obtained the controlled substances; and

(d) The full name, address, and registration number of the person who possessed the controlled substances prior to the applicant, if known.

(B) The executive director, or his/her designee, shall authorize and instruct the applicant to dispose of the dangerous drugs which are controlled substances in one of the following manners:

(1) By transfer to persons registered under Chapters 3719. and 4729. of the Revised Code, and authorized to possess the controlled substances;

(2) By destruction in the presence of a state board of pharmacy officer, agent, or inspector or other authorized person; or

(3) By such other means as the state board of pharmacy may determine to assure that the controlled substances do not become available to unauthorized persons.

(C) In the event that a registrant is required regularly to dispose of dangerous drugs which are controlled substances, the executive director may authorize the registrant to dispose of such controlled substances, in accordance with paragraph (B)(1) of this rule, without prior approval of the state board of pharmacy in each instance on the condition that the registrant keep records of such disposals and file periodic reports with the state board of pharmacy summarizing the disposals made by the registrant. In granting such authority, the executive director may place conditions on the disposal of dangerous drugs which are controlled substances including, but not limited to, the method of disposal and the frequency and detail of reports.

4729-9-10 OCCASIONAL SALE

The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a drug by a pharmacist who is a terminal distributor of dangerous drugs or is employed by a terminal distributor of dangerous drugs and the buyer shall be a wholesale distributor of dangerous drugs, a terminal distributor of dangerous drugs, or a prescriber as defined in section 4729.01 of the Revised Code.

The total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule shall not exceed five per cent of the total value of dangerous drugs purchased by the terminal distributor of dangerous drugs during the same calendar year. In addition, the total amount of controlled substances sold pursuant to this rule shall not exceed the allowable amount as specified in ~~section~~ 21 C.F.R. 1307.11 ~~of the Code of Federal Regulations~~.

The value of the dangerous drugs shall be based on the cost of the dangerous drugs to the terminal distributor of dangerous drugs.

4729-9-16 MINIMUM REQUIREMENTS FOR WHOLESALERS

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio~~.~~:

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a wholesale distributor of dangerous drugs:

(1) The name, full business address (not a post office box), and telephone number;

(2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs;

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency);

(5) The full name(s) of the owner and/or operator of the licensee, including:

(a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;

(b) If a partnership, the full name of each partner, and the name of the partnership;

(c) If a corporation, the full name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;

(d) If a government agency, the name of the agency, and the full name of each officer and director of the agency.

(6) If the entity making application for a wholesale distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. This information will be used as part of the consideration in licensing the entity by the Ohio state board of pharmacy. The Ohio board will respond to inquiries of a similar nature from other states about licensees in Ohio.

(7) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license will not be issued until the owner(s), or if incorporated the officers, of the wholesale operation submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. Additionally, a criminal records check is required every time there is a change in officers. The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The owner(s) or officers may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or if

located outside of Ohio they may submit ink fingerprint impressions as instructed on a form provided by the board.

(B) Prior to the end of the licensing period, a renewal application requesting such information as the state board of pharmacy may require will be sent to the address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the established deadline.

(C) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17 of the Administrative Code;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(D) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lighted.

(3) Entry into areas where dangerous drugs are held shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all stored drugs.

(F) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.

(G) All returned, damaged, and outdated dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to their supplier.

(2) Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

(1) These records shall include but not be limited to the following information:

(a) The source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The identity and quantity of the drugs received and distributed or disposed of.

(c) The dates of receipt and distribution of the drugs.

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.

(e) A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.

(i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.

(b) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must first send notification to the board.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated dangerous drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

(J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. When there is a change in the designated contact person to whom communications with the state board of pharmacy may be directed, the board shall be notified of the new contact person within thirty days on a board approved form. This notice to the board shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.

(K) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(L) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy designated agents, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Any entity making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

(M) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(N) The state board of pharmacy shall be notified of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant being used or implemented.

4729-9-26 CRIMINAL RECORDS CHECK FOR PAIN MANAGEMENT CLINICS

Pursuant to division (B) of section 4729.552 of the Revised Code, a new terminal distributor of dangerous drug license with a pain management clinic classification will not be issued until the physician owner(s), or if incorporated the physician officers, of the pain management clinic submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. Additionally, a criminal records check is required every time there is a change in ownership for each new owner(s) or officer(s). The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations (FBI) records check. The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The physician owner(s) or physician officers must submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code. Physician owner(s) or physician officers are required to have all employees submit to a BCI&I and FBI criminal records check to ensure that no person has been previously convicted of, or pleaded guilty to a theft offense that would constitute a felony as described in division (K)(3) of section 2913.01 of the Revised Code or a felony drug abuse offense as defined in section 2925.01 of the Revised Code. Employees must submit electronic fingerprint impressions to the physician owner(s) or physician officers pursuant to rule 4729-4-04 of the Administrative Code.

4729-37-03 ENTITIES REQUIRED TO SUBMIT INFORMATION

The following entities are required to submit the specified dispensing and wholesale sale information to the board of pharmacy for the drug database:

(A) All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to outpatients residing in this state.

(B) All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to all outpatients.

(C) All wholesalers licensed as a wholesale distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale ~~to individual prescribers within this state, or to locations other than institutional facilities that are licensed as a terminal distributor of dangerous drugs where prescribers practice~~ shall report those drug transactions.

(D) All pharmacies licensed as a terminal distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale ~~to prescribers within this state, or to locations other than institutional facilities that are licensed as a terminal distributor of dangerous drugs where prescribers practice~~ shall report those drug transactions.

(E) All prescribers, except veterinarians, located within this state shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are personally furnished to outpatients.

~~The board of pharmacy shall identify the terminal distributors of dangerous drugs locations where prescribers practice and provide this information to all entities required to report sales at wholesale.~~

4729-37-04 INFORMATION REQUIRED FOR SUBMISSION

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule 4729-37-03 of the Administrative Code that dispense drugs identified in rule 4729-37-02 of the Administrative Code to outpatients residing in this state must report the following dispensing information to the board of pharmacy:

(1) Pharmacy drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

(10) Prescriber's full name (first name and last name);

(11) Prescriber's drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(12) Date prescription was issued by the prescriber;

(13) Date the prescription was dispensed by the pharmacy;

(14) Indication of whether the prescription dispensed is new or a refill;

(15) Number of the refill being dispensed;

(16) National drug code of the actual drug dispensed;

(17) Quantity of drug dispensed;

(18) Number of days' supply of drug dispensed;

(19) Serial or prescription number assigned to the prescription order; and

(20) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial ~~pharmacy benefit manager (PBM)~~ insurance, ~~major medical,~~ or workers' compensation.

(B) Prescribers pursuant to paragraph (E) of rule 4729-37-03 of the Administrative Code that personally furnish drugs identified in rule 4729-37-02 of the Administrative Code to outpatients must report the following dispensing information to the board of pharmacy:

(1) Prescriber drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Prescriber full name (first and last name);

(3) Prescriber address;

(4) Prescriber telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

(10) Date the drug was personally furnished by the prescriber;

(11) National drug code of the actual drug dispensed;

(12) Quantity of drug dispensed;

(13) Number of days' supply of drug dispensed; and

(14) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation.

(~~B~~C) Wholesalers and pharmacies pursuant to paragraphs (C) and (D) of rule 4729-37-03 of the Administrative Code that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale must at least report the following information to the board of pharmacy in the ~~following sequence~~ format described in rule 4729-37-06 of the Administrative Code:

(1) Wholesaler or pharmacy drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;

(2) Purchaser's drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;

(3) National drug code number of the actual drug sold;

(4) Quantity of the drug sold;

(5) Date of sale~~.~~; and

(6) Transaction identifier or invoice number.

4729-37-05 ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF DISPENSING INFORMATION

(A) All pharmacy dispensing information or prescriber personally furnishing information required to be submitted to the board of pharmacy pursuant to ~~paragraph (A) of~~ rule 4729-37-04 of

the Administrative Code must be transmitted in the format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs.

(B) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to ~~paragraph (A) of~~ rule 4729-37-04 of the Administrative Code they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The pharmacy or prescriber must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

4729-37-06 ELECTRONIC FORMAT REQUIRED FOR THE TRANSMISSION OF WHOLESALE DRUG SALES

(A) All wholesale data required to be submitted to the board of pharmacy pursuant to paragraph (B) of rule 4729-37-04 of the Administrative Code must be transmitted in ~~a comma delimited ASCII text file~~ the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System (ARCOS)" or other mutually acceptable format.

(B) In the event that a wholesaler or pharmacy cannot electronically transmit the required information pursuant to paragraph (B) of rule 4729-37-04 of the Administrative Code they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The wholesaler or pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

4729-37-07 FREQUENCY REQUIREMENTS FOR SUBMITTING DRUG DATABASE INFORMATION

(A) A pharmacy or prescriber that has possessed a reported drug (including a sample drug) within the previous two years shall submit to the board of pharmacy, at least weekly, either of the following:

(1) All drug dispensing and personally furnishing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code ~~shall be submitted at least weekly. The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than eight days after the date of the dispensing.~~

(2) A "Zero Report", if a pharmacy has no drug dispensing information or a prescriber has no personally furnishing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code.

(B) ~~If a pharmacy has no drug dispensing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code, the pharmacy shall submit a "Zero Report" during the regular reporting cycle.~~ The dispensing report, the personally furnishing information, or the "Zero Report" shall be consecutive and inclusive from the last date and time that information was submitted and shall be reported no later than eight days after the last date reported on the previous report.

(C) If a pharmacy or prescriber ceases to possess any reported drug (including a sample drug), the responsible person may notify the board of pharmacy in writing. If the board is notified of the change, the pharmacy or prescriber is not required to submit a "Zero Report" until the pharmacy or prescriber possesses a reported drug (including a drug sample).

(D)All wholesale drug sale information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted monthly as follows:

(1) During the first through the tenth day of each month; and

(2) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than forty days after the date of the wholesale sale.

(~~D~~E) In the event that a wholesaler, prescriber, or pharmacy cannot submit the required information as described in this rule, the responsible person ~~they~~ must immediately contact the board of pharmacy to determine a mutually acceptable time for submission of information. The reasons for the inability of the wholesaler, prescriber, or pharmacy to submit the required information must be documented ~~document~~ in writing to the board of pharmacy ~~the reasons for their inability to submit the required information~~.

4729-37-11 CORRECTIONS TO THE DRUG DATABASE

(A) Drug dispensing and wholesale drug sale information must be submitted to the drug database in an accurate and timely manner pursuant to rule 4729-37-07 of the Administrative Code.

(B) If the omission of drug dispensing or wholesale drug sale information is discovered, the omitted information must be submitted to the board of pharmacy by the ~~licensee~~ pharmacy, prescriber, or wholesaler during the next ~~scheduled~~ reporting time period after the discovery.

(C) If erroneous drug dispensing or wholesale drug sale information is discovered, the corrected information must be submitted to the board of pharmacy by the ~~licensee~~ pharmacy, prescriber, or wholesaler during the next ~~scheduled~~ reporting period after the discovery. If the erroneous information was discovered by the licensee, the licensee must notify the board immediately by telephone of the error and submit written documentation that identifies the erroneous information.

(D) If the omission of data or erroneous data is the result of a computer programming error, the ~~licensee~~ pharmacy, prescriber, or wholesaler must notify the board of pharmacy immediately by telephone and submit written documentation. The documentation shall fully describe the error and propose a date for submitting the corrected drug information. The board will review the written documentation to assure compliance with paragraph A of this rule.